Baxter

Service Bulletin

Product Code(s) Affected: 1M8550/1M8550R
Product Name: Auto Syringe AS50 Infusion Pump

Usage: (X) Internal / (**X**) External

Title: Auto Syringe AS50 Infusion Pump Rear Case Inspection and Replacement

1.0 PURPOSE

Provide instructions for inspection of AS50 Rear Case Assemblies installed in AS50 Volumetric Infusion Pumps and part numbers AAS5001531RP, AAS5001530RPand A069160000RP for presence of incorrectly assembled ESD Squares.

2.0 APPLICABILITY

Baxter Service Centers
These service instructions are applicable to Baxter Service Centers, and Field Service Engineers providing service for the Auto Syringe AS50 Infusion Pumps.

Baxter trained Self-Servicing customers
These service instructions are provided to detail the process to inspect the Rear Case Assembly ESD squares of the AS50 Infusion Pump.

Implementation of these instructions is an optional alternative to sending the pump to the Baxter Service Center for inspection.

Opting to perform this service bulletin acknowledges agreement to **remove all Auto Syringe AS50 Volumetric Infusion Pumps** with incorrectly assembled ESD Squares and return the Customer Inspection Documentation to Baxter within **30 days** of receipt of this service bulletin; and replacement of affected rear case assemblies within 6 months.

2.1 Applicable Documents

AS3AB3001	Auto Syringe AS50 Infusion Pump Service Manual

3.0 BACKGROUND

On September 5, 2008 Baxter Healthcare Corporation communicated an Urgent Product Recall, 2008-043 MD, concerning the AS50 Infusion Pump product codes 1M8550 and 1M8550R serviced or repaired with part numbers AAS5001530RP, AAS5001531RP, or A069160000RP from November 1, 2007 to July 29, 2008.

The Rear Case assemblies were manufactured with ESD grounding squares that may have been manufactured with the adhesive applied to the incorrect side resulting in exposure of the conductive surface of the I/O board. Pumps that have been serviced or repaired with these components could short circuit resulting in a loss of audio and/or interruption of therapy.

4.0 GENERAL INFORMATION

4.1 Materials Required

Replacement Rear Case Assembly Part Numbers AAS5001531RP, or AAS5001530RP, or A069160000RP

4.2 Warnings and Cautions

! WARNING ! Repairs, upgrades and inspections shall be performed by qualified Baxter employees or Baxter-trained qualified personnel, using only Baxter specified parts, and servicing instructions or manuals that are provided by Baxter.

CAUTION! The pump contains ESD susceptible components. Establish appropriate ESD controlled workspace prior to conducting this procedure. This includes use of a properly grounded anti-static mat and a grounded wrist strap.

5.0 PROCEDURE

5.1 Remove the rear case assembly per the instruction in the Auto Syringe AS50 Infusion Pump Service Manual

5.2 Remove the I/O board per the instructions in the Auto Syringe AS50 Infusion Pump Service Manual

5.3 Inspect the ESD Grounding Squares shown in the illustrations below.

Critical Note: Baxter trained Self-Servicing customers only

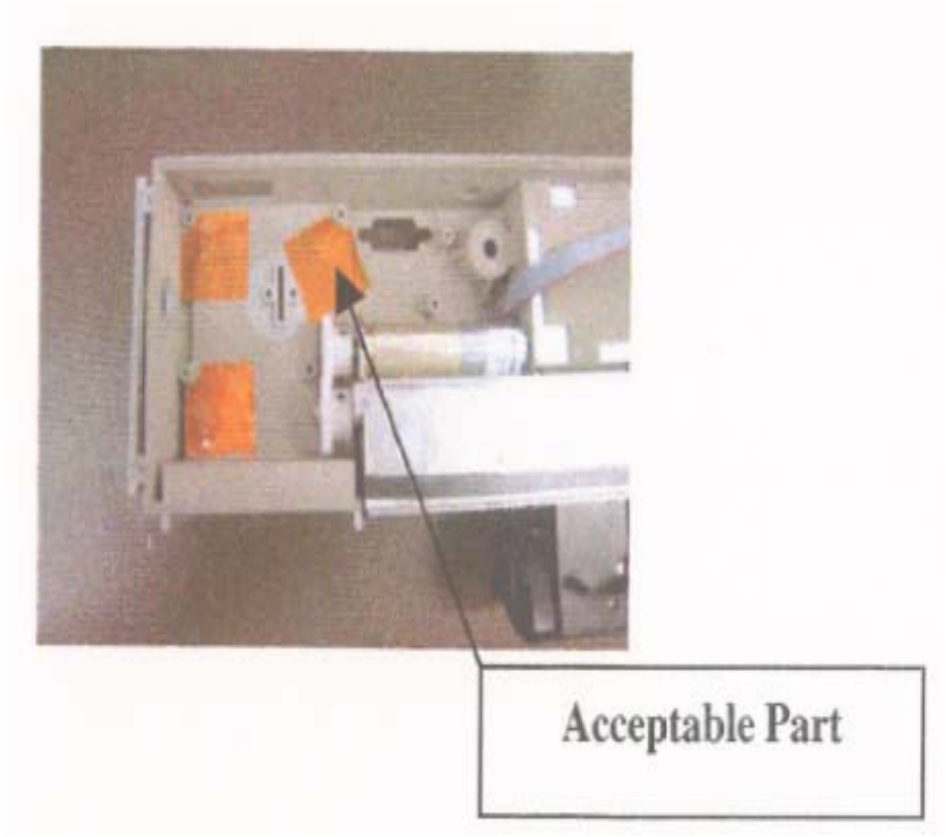
If the grounding squares are non-conforming, remove the pump from service, complete the Customer Inspection Documentation Form, and return the form to Baxter within **30 days** of receipt of this service bulletin.

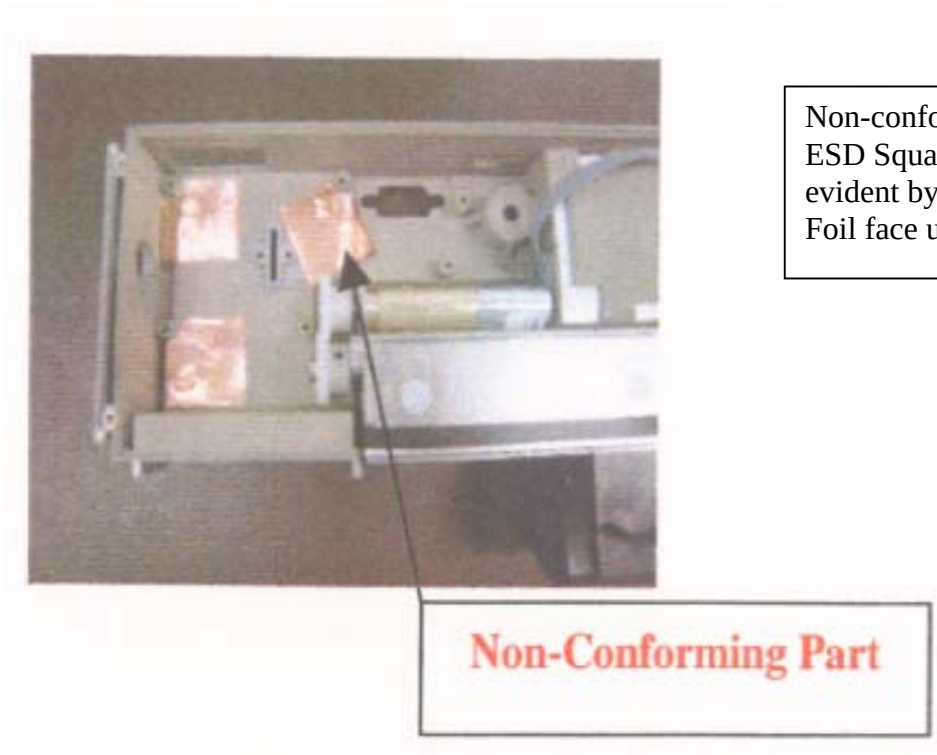
5.4 Upon receipt of replacement rear case assemblies from Baxter, verify the replacement rear case assembly grounding squares are correctly assembled per the illustrations below.

5.5 Follow the instructions in the service manual to replace the non-conforming rear case assemblies.

5.6 Mark “6” on the device configuration label, located inside the battery cover.

5.7 Perform required Calibration, Functional and Final Testing prior to placing device back into service.





Non-conforming ESD Squares are evident by Copper Foil face up.

6.0 DOCUMENTATION

Baxter Service Centers

Complete documentation of Calibration and Functional testing as defined by internal Service Procedures:

AS5AB1004	AS50 Calibration Procedure
AS5AB1009	AS50 Functional Test Procedure

Completion of service activity defined by this Service Bulletin will be documented on the Service Order.

Baxter trained Self-Servicing customers

Complete documentation of Calibration and Functional testing as indicated by AS3AB3001Auto Syringe AS50 Infusion Pump Service Manual or per facility operating procedure.

Complete the Customer Inspection Documentation Form and Fax to 1 (847) 270 5457 within 30 days of receipt of this service bulletin. Receipt of this documentation by Baxter will prevent repeat requests for information.

Customer Inspection Documentation Form

Baxter

AS50 Infusion Pump, Product Codes 1M8550 and 1M8550R
AS50 Infusion Pump Rear Case Assembly Product Codes AAS5001530RP/ AAS5001531RP/A069160000RP

URGENT PRODUCT RECALL - CUSTOMER SERVICE REPLY FORM

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. Please check all that apply. A fax cover sheet is not required.

Facility Name and Address:	

☐ We have examined our inventory and completed inspection of AS50 pumps. The AS50 pumps as listed in this notification have been removed from service until such time that remediation is complete. Please use multiple reply forms if necessary.

Serial Number	Serial Number	Serial Number	Serial Number

We understand the contents of the Service Bulletin and performed the actions as outlined.

Required Fields:

Reply Completed By: **(Signature/Date)**	
Name: ***(Please Print Name)***	
Title: ***(Please Print)***	
Telephone Number: **(Including Area Code)**	